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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/900,241 | 07/06/2001 | Andrew Kerr | Kerr-5 | 5997 |
| 1218 | 7590 | 07/13/2004 | EXAMINER | |
| CASELLA & HESPOS 274 MADISON AVENUE NEW YORK, NY 10016 | | | BLANCO, JAVIER G | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,241

Applicant(s)

KERR, ANDREW

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/24/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 24, 2004 has been entered.

Drawings

2. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Response to Amendment

3. Applicant's cancellation of claims 4 and 27 in the reply filed on June 24, 2004 is acknowledged.

Claim Objections

4. Claims 25 and 26 are objected to because of the following informalities:

a. Regarding claim 25, please insert --of the graft means-- after "axial end" (see line 15).

Appropriate correction is required.

b. Regarding claim 26, please insert --axial-- in front of "ends" (see line 4). Appropriate correction is required.

Declaration under 37 CFR 1.132

5. The Declaration under 37 CFR 1.132 filed June 24, 2004 is insufficient to overcome the rejection of claims 25 and 26 based upon Anderson et al. '526 document as set forth in the last Office action because:

a. The Examiner conducted a word search for "butt joint" in www.onelook.com dictionary search.

(i) Several general-purpose dictionaries define "butt joint" as: (i) *"a joint made by fastening the parts together end-to-end without overlap"*, and as (ii) *"a joint formed by two abutting surfaces placed squarely together"*.

(ii) A tech dictionary defines "butt joint" as *"a weld where the two panels are not overlapped but fit against each other end to end"*.

(iii) An art dictionary defines "butt" as *"to adjoin without overlapping, as for example, two pieces of film or other material, or two colors of ink"*.

b. The Examiner conducted a word search for "lap joint" in www.onelook.com dictionary search. Several general-purpose dictionaries define "lap joint" as *"a joint made by overlapping two ends or edges and fastening them together"*.

c. Anderson et al. '526 disclose in column 10, lines 2-5 and lines 8-10 the stent/graft assembly as having a small cross-section for ease of introducing into a blood vessel. Given that Anderson et al. disclose/describe a stent/graft assembly comprising the claimed limitations set forth in claims 25, 26, and 3 (specifically the "butt joint" connection between the stent(s) and the graft), it will be inherent that it will perform as indicated in the newly added functional language. Therefore, the "butt joint" connection of the stent/graft assembly of Anderson et al. will enable a smaller

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cross-section allowing the stent/graft assembly to be introduced more easily into the blood vessel.

d. The Examiner conducted an EAST word/text search for “butt joint”. Several documents in the medical art showed the same definition for a “butt joint”. Some examples are:

(i) As seen in Figure 15, US 5,928,281 teaches a heart valve with a butt joint 122 (see column 10, lines 49-56, claims 12 and 27). The reference teaches said butt joint provides a slimmer profile for the heart valve (see entire document).

(ii) As seen in Figure 12, US 6,565,599 teaches a stent having a link 90 attached to a metal ring by joint. The reference distinguished between a lap joint versus a butt joint (see column 7, lines 46-50).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 25 and 3 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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A tubular graft means having "*a first axial end extending between the inner and outer circumferential surfaces thereof*" (see lines 12-13) was not disclosed/described in the specification or figures.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 25 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 25, newly added limitation "*a first axial end extending between the inner and outer circumferential surfaces thereof*" (see lines 12-13) is vague and confusing, rendering the claim indefinite.

The claim language of claim 25, lines 5-8 discloses tubular stent means "*having inner and outer circumferential surfaces and opposite first and second axial ends extending between the inner and outer circumferential surfaces*". By contrast, the claim language of claim 25, lines 12-13 disclose tubular graft means having "*a first axial end extending between the inner and outer circumferential surfaces thereof*". How could an axial end extend between inner and outer circumferential surfaces?

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 25, 26, and 3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Anderson et al. (US 5,800,526 A).

As seen in Figures 9, 10, and 12, Anderson et al. disclose an endovascular stent/graft assembly comprising stent means (stent 56 and stent 58) having opposite first and second axial ends, and graft means (graft 52) having first and second axial ends directly contacting first and second relatively healthy sections of a blood vessel (graft is bridging an aneurysm). The first axial end of graft 52 is fixedly connected with the second axial end of stent 58 for achieving a substantially end-to-end connection (see figures; see entire document). Said end-to-end connection may include overlapping (see Figures 9, 10, and 12) and the use of an adhesive (see column 11, lines 1-10 and lines 57-60). Said end-to-end connection is also disclosed/described by Anderson et al. as an end-to-end connection without overlap (= “butt joint”: see column 11, lines 10-14). It should be noted that Merriam-Webster dictionary defines “butt joint” as *“a joint made by fastening the parts together end-to-end without overlap and often with reinforcement”* (this was addressed in the last Office Action). Anderson et al. further disclose/describe said “butt joint” connection as having all of the stent extending out of the graft (see column 11, lines 10-14). Said teaching further corroborates/validates the dictionary definition of “butt joint”.

With regards to newly added claim limitation: “whereby the end-to-end connection without overlap enables a smaller cross-section than a connection with overlap so that the

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endovascular stent/graft assembly can be introduced more easily into the blood vessel”, it should be noted:

- a. Anderson et al. disclose in column 10, lines 2-5 and lines 8-10 the stent/graft assembly as having a small cross-section for ease of introducing into a blood vessel.
- b. Given that Anderson et al. disclose/describe a stent/graft assembly comprising the claimed limitations set forth in claims 25, 26, and 3 (specifically the “butt joint” connection between the stent(s) and the graft), it will be inherent that it will perform as indicated in the newly added functional language. Therefore, the “butt joint” connection of the stent/graft assembly of Anderson et al. will enable a smaller cross-section allowing the stent/graft assembly to be introduced more easily into the blood vessel.
- c. Claims in a pending application should be given their broadest reasonable interpretation. *In re* Pearson, 181 USPQ 641 (CCPA 1974).

12. Claim 26 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Gifford et al. (US 6,383,171 B1; previously cited in the Office Action mailed August 28, 2002).

As seen in Figures 3, 4, 6B, 19, 21-23, 26A, 26E, and 27-29, Gifford et al. disclose an endovascular stent-graft assembly for repairing a section of a blood vessel that has an aneurysm (see column 1, lines 7-22; column 2, lines 6-8; see entire document), said blood vessel having first and second relatively healthy sections adjacent and on opposite ends of said aneurysm, said assembly comprising (i) a tubular graft having inner and outer circumferential surfaces and first and second axial ends extending between the inner and outer circumferential surfaces, and (ii) a stent (anchor 12) having first and second axial ends. Said first axial end of the graft being connected in end-to-end relationship with said second axial end of the stent without overlap to

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define a connection (see Figures 3, 4, 6B, 19, 21-23, 26A, 26E, and 27-29; see column 4, lines 48-59; column 6, lines 33-35; column 6, line 60 to column 7, line 7), whereby the end-to-end connection without overlap enables a smaller cross-section than a connection with overlap so that the endovascular stent-graft assembly can be introduced more easily into the blood vessel (see entire document).

Response to Arguments

13. Applicant's arguments filed June 24, 2004 have been fully considered but they are not persuasive. The Response to Applicant's arguments have been incorporated with the 102(b) rejection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Huynh et al. (US 5,928,281 A), Hong et al. (US 6,565,599 B1), Elliot (US 6,712,843 B2), and Kang et al. (WO 01/56501 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the

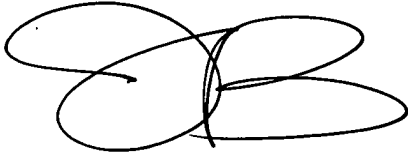

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organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

July 10, 2004

A stylized, handwritten signature consisting of several overlapping loops and a long horizontal stroke.A handwritten signature in cursive script, appearing to read 'David H. Willse'.

David H. Willse
Primary Examiner